K010958

MAY 1 8 2001

II. 510K SUMMARY IN ACCORDANCE WITH SMDA '90

SUBMITTER:	DIASOL INC. 13212 RAYMER ST. NORTH HOLLYWOOD, CA 91605 PHONE (818) 255-1800 FAX (818) 982-8539
CONTACT	MONICA ABELES
DATE SUMMARY WAS PREPARED	March 6, 2001
NAME OF DEVICE	FISTULOK AV FISTULA NEEDLE GUARD
COMMON NAME	AV FISTULA NEEDLE GUARD
CLASSIFICATION NAME	NEEDLE, HYPODERMIC, SINGLE LUMEN, PROTECTOR 880.5570 CLASS II
PERFORMANCE STANDARD	NONE ESTABLISHED UNDER 514 OF FDA
PREDICATE DEVICE	PLATYPUS AV FISTULA NEEDLE PROTECTOR

DEVICE DESCRIPTION:

FISTULOK IS A SINGLE USE, DISPOSABLE, NONSTERILE DEVICE INTENDED FOR USE WITH ANY AV FISTULA NEEDLE. WHEN MOUNTED ON THE NEEDLE AND ACTIVATED, IT AIDS IN THE PREVENTION AGAINST ACCIDENTAL NEEDLESTICKS.
OUR DEVICE HAS THE SAME INTENDED USE AS THE IDENTIFIED PREDICATE DEVICE.
The device can be mounted prior to start of the dialysis process or at the end, just before the needle extraction. Once the device is mounted on the tubing and slides to the tip of the needle hub, it is immobilized in this position by pressing on the clamp. The needle is extracted by sliding into protected device while pressing on the wings until a click is heard.
Fingers are always kept behind or away from the needle.

It is a real single-handed procedure; only two fingers are needed to press on the extended wing portion while the needle is encapsulated. Once the device is activated, it becomes very difficult to tamper with the device.
The fingers are completely away from the needle at all times.

PERFORMANCE DATA FOR THE PREDICATE DEVICE WERE NOT AVAILABLE.
WE COMPARED OUR DEVICE TO OTHER SIMILAR DEVICES CURRENTLY IN COMMERCIAL USE AND SET OUR OWN STANDARDS FOR THE PERFORMACE TESTS OF THE PROTECTED DEVICE PART.

OUR DEVICE HAS PERFORMED VERY WELL DURING SIMULATED USE TRIALS.
IT PERFORMED SUPERIOR TO THE PREDICATE WITH REGARDS TO THE SINGLE HANDED OPERATION AND ADAPTABILITY TO HARD TO REACH SITUATIONS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 8 2001

Ms. Monica Abeles
President
Diasol Incorporated
13212 Raymer Street
North Hollywood, California 91605

Re: K010958
Trade/Device Name: Fistulok Fistula Needle Protection
Regulation Number: 880.5570
Regulatory Class: II
Product Code: FMI
Dated: March 30, 2001
Received: March 30, 2001

Dear Ms. Abeles:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K010958

Diasol Inc.

c. STATEMENT OF INTENDED USE

510k NUMBER

DEVICE NAME: FISTULOK

INDICATIONS FOR USE:

Fistulok is intended for use with AV Fistula needles for hemodialysis and aphaeresis procedures as a means of protection against accidental needle sticks.
The safety shield when activated provides a safe closure of the needle though aiding in needlestick injury prevention.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use---✓---
Per 21 CFR 801.109

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010958